UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

JAMES W. NOLEN,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**Case No. 3:19-cv-0799**
	)	**Judge Aleta A. Trauger**
C.R. BARD INCORPORATED and BARD PERIPHERAL VASCULAR INCORPORATED,	)	
	)	
Defendants.	)	
	)	

MEMORANDUM

C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. (collectively, "Bard") have filed a Motion for Summary Judgment (Doc. No. 66), to which James W. Nolen has filed a Response (Doc. No. 84), and Bard has filed a Reply (Doc. No. 91). For the reasons set out herein, the motion will be granted in part and denied in part.

I. BACKGROUND

Bard is the manufacturer of the Meridian Filter, a small device intended to be inserted into the inferior vena cava ("IVC") in order to intercept blood clots before a clot can reach the lungs and cause a potentially catastrophic pulmonary embolism ("PE"). (Doc. No. 83 ¶¶ 1–2, 6–7.) Meridian is a "retrievable" filter, meaning that it is intended to be capable of being removed at some future date after it has been installed. (*Id.* ¶ 7.) IVC filtration is not the only strategy for treating patients at a high risk of PE, and there may be legitimate reasons for electing to remove a filter after its initial placement. The Meridian Filter, moreover, has never been the only IVC filter available. (*Id.* ¶ 4.)

The Meridian Filter consists of two tiers of struts referred to as its "arms" and "legs," emanating from a small shared structure, with which it forms what could loosely be described as a squid-like shape. The filter can be introduced into the IVC using a catheter inserted through a small puncture in the jugular vein or femoral vein. (*Id.* ¶ 9.) When the Meridian Filter functions as intended, the arms and legs widen and anchor it to the walls of the IVC, forming a firmly-stationed barrier to blood clots, through which ordinary blood can safely pass. It is possible, however, for the filter not to function as intended and instead to tilt, migrate, fracture, or even perforate the walls of the IVC. (*Id.* ¶¶ 10–11.) Bard maintains that these risks are inherent in the use of IVC filters; Nolen disagrees and argues that the Meridian Filter is unusually unsafe, and he has produced evidence that the frequency of such unwanted events differs considerably between different filter devices. (*Id.* ¶ 12.)

As a prescription medical device, the Meridian Filter is subject to "[t]he Medical Device Amendments of 1976 ('MDA'), 21 U.S.C. §§ 360c–360k, 379–379a, [which] establish[] the framework for federal regulation of medical devices. As amended, the MDA requires the FDA to place a device into one of three classes reflecting different levels of regulation." *Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1003 (7th Cir. 2020). Meridian is a Class II device that was approved by the FDA as "substantially equivalent" to a previously approved device, through what is known as the agency's § 510(k) medical device approval process. *See id.* (discussing § 510(k) process). Specifically, the Meridian Filter is part of a broader line of Bard IVC filters, traceable back to the Bard Recovery filter, which was predicated on the Bard Simon Nitinol Filter ("SNF") and, according to Bard, the Greenfield Filter. (Doc. No. 92 ¶¶ 5, 7.) The Meridian Filter itself received § 501(k) clearance in 2011. (*Id.* ¶ 4.)

Nolen is a Tennessee patient who suffered from recurrent deep vein thrombosis ("DVT"), a condition that increased his likelihood of forming a blood clot that could eventually pass through his circulatory system and lead to a PE. (Doc. No. 83 ¶¶ 13–15.) He was admitted to Horizon Medical Center ("Horizon") for DVT in his left leg on July 3, 2012. (*Id.* ¶ 13.) By that point, his history of DVT had proven to be persistent, despite his use of anticoagulant medications. His primary care physician, accordingly, referred him for evaluation of the possibility of installing an IVC filer. (*Id.* ¶¶ 14–15.)

Ultimately, Nolen consented to the installation of a Meridian Filter by Dr. Patrick Moulton. Nolen's patient record states that Dr. Moulton informed Nolen of the "indications, procedure, and possible complications, including but not limited to bleeding, infection, and filter migration" associated with the device. (*Id.* ¶ 16.) Nolen testified that he did not remember discussing those matters with Dr. Moulton and that he primarily recalled being told that the implantation of the filter could save his life. (*Id.*) The implantation procedure itself was uneventful, and Nolen was discharged the next day. (*Id.* ¶¶ 19–20.) Dr. Moulton has since died and has therefore been unable to testify in this case. (*Id.* ¶ 17.)

Years passed without Nolen noticing or suspecting that anything seemed to be wrong with the filter. (*Id.* ¶ 21.) Eventually, Nolen's cardiologist, Dr. Ehab Kasasbeh, recommended that he be evaluated for removal of the filter. (*Id.* ¶ 22.) On April 10, 2018, Dr. John Barraza ordered a computed tomography ("CT") scan of Nolen's abdomen and chest to assess his condition, including the status and placement of the filter. (*Id.* ¶ 23.) The scan revealed that the filter was still in the location expected, but that it had tilted and that some of its legs were protruding through and out of the IVC. (*Id.* ¶ 24.) The reading radiologist nevertheless concluded that there were "[n]o

contraindication[s] to IVC filter removal." (*Id.* ¶ 25.) After consultation, Nolen elected for Dr. Barraza to remove the filter. (*Id.* ¶ 26.)

On May 15, 2018, Dr. Barraza attempted to remove the filter with a snare, but he was unable to do so, because the device's legs were too deeply imbedded in the IVC surface. (*Id.* ¶ 27.) He decided to try a "loop snare," but the loop snare was also unsuccessful. A third option, using forceps, was not possible at the time because the particular forceps needed were unavailable. (*Id.* ¶¶ 29–30.) The filter was therefore not removed and remains unremoved today. (*Id.* ¶¶ 31–32.) Nolen concedes that he has not consulted with any physician regarding the possibility of another removal attempt. (*Id.* ¶ 34.)

Nolen has testified that he does not know if he has suffered any adverse health consequences from the continued presence of the Meridian Filter. (*Id.* ¶ 32.) Nolen's expert, Dr. David C. Feldstein, M.D., testified that, based on the records he has reviewed, he could not say conclusively whether Nolen was suffering from any ill effects related to the filter other than the simple fact that the filter has, in essence, become asymptomatically tilted and stuck. According to Dr. Feldstein, contrast imaging might (or might not) reveal that Nolen is suffering from increased clotting around the site of the filter due to the perforation of the IVC. Dr. Feldstein also noted that, even if Nolen is currently asymptomatic, the fact that the filter has become so embedded in the IVC means that the IVC has, at least to some degree, been damaged. (*Id.*) In any event, Nolen maintains that, even if he has not yet suffered additional symptoms related to the tilting of the filter and the perforation of his IVC, he has been placed at greater risk of future adverse events, and the perforation and continued presence of the tilted filter will require him to monitor his IVC with recurrent, expensive imaging in order to detect any dangerous worsening of the situation. (Doc. No. 92 ¶¶ 2–3.)

Dr. Feldstein testified that he did not "know what facts or data [Dr. Moulton] considered in deciding which filter to use" and that he therefore could not conclusively "say whether [Dr. Moulton] would have made a different decision about which filter to use if he [had] had the information of [Dr. Feldstein's] opinions." (Doc. No. 83 ¶ 50.) Dr. Feldstein did state, however, that, in his opinion, "had Bard provided a warning that communicated the true nature and extent of the increased risk of the Meridian Filter of causing an adverse event, no reasonable physician responsible for implanting IVC filters would have used the Meridian Filter." (*Id.*) According to Dr. Feldstein, physicians, such as Dr. Moulton, rely on medical device manufacturers to adequately test their devices for risks and to warn physicians about those risks in order to assist in the physician's decisionmaking. (Doc. No. 92 ¶ 36.) Furthermore, Nolen himself has declared that, "[i]f [he] had been told there were safer alternatives to the Meridian Filter, [he] would have asked to have a safer alternative filter implanted." (Doc. No. 83-21 at 2.)

The Meridian Filter is accompanied by official Instructions for Use ("IFU") that include a list of potential complications, but the IFU do not provide any warning that the Meridian might be riskier than other, alternative IVC filters. (Doc. No. 83 ¶ 12.) Nolen, however, maintains that Bard was aware that the G2 line of filters, of which the Meridian Filter was the final iteration, posed a disproportionate risk of migration and other complications, as compared to other filters, including the SNF. Nolen sets forth a lengthy body of alleged facts in support of his position, but Bard objects that those facts are irrelevant to its motion, in light of the limited grounds on which it is seeking summary judgment. (Doc. No. 92 ¶¶ 9–34, 37–38.) Nolen also cites various issues with Bard's use of the § 510(k) process, but Bard again objects that those allegations are irrelevant to the grounds for summary judgment that it has raised. (*Id.* ¶¶ 45–55.)

There is currently a multidistrict litigation ("MDL") proceeding regarding Bard IVC filters in the District of Arizona. On October 15, 2018, Nolen filed a form Complaint to join the MDL. (*Id.* ¶ 43; *see* Doc. No. 1.) On August 20, 2019, the MDL court filed a Suggestion of Remand and Transfer Order ordering the plaintiffs in a number of cases, including Nolen's, to identify the U.S. District Court in which their claims would appropriately have been filed, if they had not been filed, in the first instance, to be part of the MDL. Nolen informed the court that this district would have been the appropriate forum, and the case was transferred. (Doc. No. 3; Doc. No. 5; Doc. No. 83 ¶¶ 44–45.)

Nolen originally pleaded fourteen causes of action against Bard. In his briefing, Nolen conceded that he is abandoning nine of those theories of liability, leaving five remaining—namely, Counts II, III, IV, VII, and IX. Count II is a claim for strict product liability based on a failure to warn; Count III is a claim for strict product liability based on a design defect; Count IV is a claim for negligent design; Count VII is a claim for negligent failure to warn; and Count IX is a claim for negligence *per se*. (Doc. No. 1 at 3; Doc. No. 84 at 1 n.1 (stating that Nolen "withdraws" the other claims).) Bard seeks summary judgment with regard to all claims.

II. LEGAL STANDARD

Rule 56 requires the court to grant a motion for summary judgment if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). If a moving defendant shows that there is no genuine issue of material fact as to at least one essential element of the plaintiff's claim, the burden shifts to the plaintiff to provide evidence beyond the pleadings, "set[ting] forth specific facts showing that there is a genuine issue for trial." *Moldowan v. City of Warren*, 578 F.3d 351, 374 (6th Cir. 2009); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). "In evaluating the evidence, the court

must draw all inferences in the light most favorable to the non-moving party." *Moldowan*, 578 F.3d at 374 (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986)).

At this stage, "'the judge's function is not . . . to weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial.'" *Id.* (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986)). But "[t]he mere existence of a scintilla of evidence in support of the [non-moving party's] position will be insufficient," and the party's proof must be more than "merely colorable." *Anderson*, 477 U.S. at 249, 252. An issue of fact is "genuine" only if a reasonable jury could find for the non-moving party. *Moldowan*, 578 F.3d at 374 (citing *Anderson*, 477 U.S. at 252).

III. ANALYSIS

A. Failure-to-Warn Claims (Counts II and VII)

Bard argues that Nolen's failure-to-warn claims "necessarily fail[] because he has not produced and cannot produce any evidence that an alleged failure to warn proximately caused him any injury." (Doc. No. 67 at 1–2.) Bard premises that argument, in large part, on a fact that, although important from an evidentiary standpoint, does not, in and of itself, have anything to do with the substance of Nolen's claim—the fact that Dr. Moulton's death prevents Dr. Moulton from testifying with regard to whether a stronger warning would have led him to recommend a different course of treatment. Without Dr. Moulton to testify that a stronger warning would have made a difference, Bard argues, Nolen cannot establish that the lack of a fuller warning caused him to receive the Meridian Filter, meaning that he cannot establish causation for his injuries.

In Tennessee, "actions for or on account of personal injury . . . from the manufacture, construction, design, formula, preparation, assembly, testing, service, warning, instruction, marketing, packaging or labeling of any product" are "product liability actions" subject to the

Tennessee Products Liability Act ("TPLA"). *See* Tenn.Code Ann. § 29-28-102(6). For the purposes of a failure-to-warn claim under the TPLA, "[a]n adequate warning is one calculated to bring home to a reasonably prudent user of the product the nature and the extent of the danger involved in using the product . . . . The adequacy of the warning is a question for the jury unless reasonable minds could agree on the outcome." *Evridge v. Am. Honda Motor Co.*, 685 S.W.2d 632, 636–37 (Tenn. 1985) (internal quotation marks and citations omitted).

An extra layer of complexity arises with regard to products, such as prescription drugs and medical devices, that are dispensed to laypeople under the supervision of licensed experts, such as physicians. Under the "learned intermediary" doctrine, a medical device manufacturer is required to "reasonably disclose[] to the medical profession all risks inherent in the use of the [device] which the manufacturer knew or should have known to exist." *Harwell v. Am. Med. Sys.*, 803 F. Supp. 1287, 1300 (M.D. Tenn. 1992); (internal quotation omitted); *Nye v. Bayer Cropscience*, 2009 WL 3295137, *12 (Tenn. Ct. App. Oct.14, 2009). The Tennessee Supreme Court has provided a non-exclusive list of criteria to be considered in assessing the adequacy of the warning:

> 1. the warning must adequately indicate the scope of the danger; 2. the warning must reasonably communicate the extent or seriousness of the harm that could result from misuse of the drug; 3. the physical aspects of the warning must be adequate to alert a reasonably prudent person to the danger; 4. a simple directive warning may be inadequate when it fails to indicate the consequences that might result from failure to follow it and, . . . 5. the means to convey the warning must be adequate.

Pittman v. Upjohn Co., 890 S.W.2d 425, 429 (Tenn. 1994) (*quoting Serna v. Roche Lab'ys, Div. of Hoffman-LaRoche, Inc.*, 684 P.2d 1187, 1189 (N.M. Ct. App. 1984)). However, even if the warning was in some abstract way deficient, the plaintiff must also produce "evidence that [the omitted] warning would have altered the doctor's actions and that the change in the doctor's actions would have averted the patient's injury. 'The key inquiry is whether, had additional

warnings been given, the plaintiff would not have sustained [his] injuries.'" *Payne v. Novartis Pharm. Corp.*, 767 F.3d 526, 531–32 (6th Cir. 2014) (quoting *Smith v. Pfizer Inc.*, 688 F. Supp. 2d 735, 746 (M.D. Tenn. 2010)).

Bard has not, at this stage, provided undisputed evidence that would permit the court to conclude, for summary judgment purposes, that the warnings it provided in the Meridian IFU were adequate. Although the IFU did acknowledge a risk of complications, "[a] reasonable warning not only conveys a fair indication of the dangers involved, but also warns with the degree of intensity required by the nature of the risk." *Pittman*, 890 S.W.2d at 429 (citing *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 837 (Ohio 1981)). There are disputed issues of fact regarding whether the warnings here did so. The determinative issue, therefore, is causation—specifically, whether Nolen has identified sufficient evidence to allow a reasonable jury to conclude that Dr. Moulton would have recommended a different course of treatment, such as a different IVC filter, if he had been warned in the manner that Nolen suggests.

The court concludes that Dr. Feldstein's testimony and the numerous contextual facts about the market for IVC filters that the parties have introduced are sufficient to allow a reasonable jury to conclude that the lack of a more forceful or detailed warning was a proximate and actual cause of Dr. Moulton's decision to use the Meridian Filter. Obviously, it would be preferable to have Dr. Moulton's own testimony regarding why he chose the filter that he did and what he would have done in response to more information. However, Dr. Feldstein's testimony about what a reasonable physician would have done is potentially persuasive evidence that Dr. Moulton would have acted differently. There is, moreover, nothing in the record to suggest that Dr. Moulton had any personal decisionmaking process that would depart from the ordinary concerns depicted by Dr. Feldstein. Dr. Feldstein's testimony, moreover, is accompanied by a great deal of evidence confirming the

existence of alternative courses of treatment that could have been selected instead of the Meridian Filter, including less risky competitor filters. Finally, Nolen's own testimony suggests that, if Dr. Moulton had relayed a more specific warning to him, then he would have pressed for an alternative course of treatment, regardless of Dr. Moulton's initial recommendation.

Bard's assertion that a defendant is, in effect, categorically shielded from liability for failure to warn simply because the prescribing physician has died is without support either in Tennessee's caselaw or in ordinary logic. Indeed, Bard concedes that there is no Tennessee precedent supporting such an absolute proposition. (*See* Doc. No. 67 at 8 ("[I]t does not appear that any Tennessee court has had the occasion to directly address the viability of a warning claim when the prescribing physician is deceased . . . ."). Nor is there any basis, in the Rules of Evidence or the substantive law of products liability, for concluding that first-person testimony from a prescribing physician is the *only* type of evidence suitable for establishing causation in a case such as this. There are many tools that a finder of fact might use to try to determine how a physician would have reacted to additional information, including evidence of the severity of the risk involved and the availability of alternative courses of treatment, as well as expert testimony regarding the ordinary standard of care.

It is always difficult when a key witness dies before he or she can testify in a case. The untimely death of a witness is not a new problem, though, and parties have devised various situation-specific tools for dealing with it, rather than simply throwing up their hands and concluding that the case cannot be continued in the witness's absence. Nolen's strategy of recreating the options that Dr. Moulton faced and setting forth evidence of how a reasonable physician would have reacted is an acceptable course of action and sufficient to defeat a motion

for summary judgment in this instance. The court, accordingly, will deny Bard's motion with regard to the failure-to-warn claims.

B. Design-Based Claims (Counts III and IV)

Bard argues that Nolen's claims based on the design of the Meridian Filter must fail because they are barred by Tennessee's exception to liability for design-based claims if the product at issue is useful but unavoidably dangerous and accompanied by appropriate warnings. While strict liability usually attaches to manufacturers of defective or unreasonably dangerous products for the injuries caused thereby, Tennessee courts have recognized that Comment k to the Restatement (Second) of Torts § 402A creates an exception for "unavoidably unsafe products," if certain conditions are met. *Harwell*, 803 F. Supp. at 1300; *Pittman*, 890 S.W.2d at 428–29. Pursuant to Comment k, an action does not lie against the manufacturer of such a product if the product was "properly prepared and accompanied by proper directions and warning." *Pittman*, 890 S.W.2d at 428–29; Restatement (Second) of Torts, Section 402A, cmt. k.

"Jurisdictions are split on whether" medical devices automatically qualify as unavoidably unsafe for the purposes of Comment k, "with the majority of courts favoring [a] case-by-case methodology" that looks at the details of the particular device. *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 772 (5th Cir. 2018). "Where comment k applies, a prescription drug [or device] manufacturer 'is not subject to strict liability for design defects. Instead, the manufacturer's liability is limited to manufacturing defects, for those cases in which the [drug or device] had been improperly prepared, and warning defects, where a manufacturer's failure to market a drug [or device]. . . [with] adequate warnings of its dangers renders the product defective." *House v. Bristol-Myers Squibb Co.*, No. 3:15-CV-00894-JHM, 2017 WL 55876, at *2 (W.D. Ky. Jan. 4, 2017) (quoting *Snawder v. Cohen*, 749 F. Supp. 1473,

1476 (W.D. Ky. 1990)). That limitation on liability is intended to "acknowledge[] that 'some products . . . are so beneficial and necessary that the manufacturer of these products should not, in all instances, be held strictly liable" for harm caused by the product's inherent, unavoidable risks. *Prather v. Abbott Lab'ys*, 960 F. Supp. 2d 700, 706 (W.D. Ky. 2013) (quoting *Graham by Graham v. Wyeth Lab'ys*, 666 F. Supp. 1483, 1496 (D. Kan. 1987)).

Bard may ultimately be entitled to the protection of Comment k. The availability of that protection, however, is dependent on, among other things, whether Bard adequately warned physicians regarding the heightened risks associated with the Meridian Filter. Bard has not identified undisputed facts that would support such a conclusion, and even its arguments related directly to the failure-to-warn claims focus only on causation, not the adequacy of the warnings themselves. Indeed, Bard appears to recognize that its argument regarding Comment k cannot succeed unless it also succeeds regarding failure to warn, arguing only that Nolen has no design-based claim "[i]n the absence of any viable claims regarding . . . marketing/warning." (Doc. No. 67 at 9.) As the court has already held, however, Nolen may, in fact, have a viable claim based on Bard's failure to warn. Granting summary judgment with regard to Counts III and IV would therefore be premature.[1]

C. Negligence *Per Se* Claim (Count IX)

Tennessee courts have historically recognized that "violation of [certain] statute[s] may be deemed to be negligence *per se*. " *Whaley v. Perkins*, 197 S.W.3d 665, 672 (Tenn. 2006) (quoting

[1] Moreover, as Nolen points out, Comment k is, by its own terms, an exception to *strict liability* for products that are *unavoidably* dangerous—not a defense to *negligent* design of a product that is *unnecessarily* dangerous. *See Toner v. Lederle Lab'ys, a Div. of Am. Cyanamid Co.*, 732 P.2d 297, 305 (Idaho 1987) ("Courts and commentators universally agree to [the] limitation on comment k's grant of immunity [to claims for] strict liability.") (collecting cases). Nolen has provided evidence that the Meridian Filter was unnecessarily dangerous and that the decision to market it as an alternative to less-dangerous filters was itself negligent. Therefore, even if Comment k applied to defeat the strict liability claim of Count III, Nolen might nevertheless have a negligent design claim under Count IV.

Cook ex rel. Uithoven v. Spinnaker's of Rivergate, Inc., 878 S.W.2d 934, 937 (Tenn. 1994)) (italics added). Bard has addressed Nolen's negligence *per se* claim only briefly, including Count IX in the list of claims susceptible to his arguments regarding Comment k. Nolen does not mention Count IX by name at all, although Nolen does respond generally to Bard's arguments regarding Comment k. Bard argues that that response is insufficient and that Nolen has therefore abandoned his claim for negligence *per se*.

As Bard points out, "a plaintiff is deemed to have abandoned a claim when a plaintiff fails to address it in response to a motion for summary judgment." *Brown v. VHS of Mich., Inc.*, 545 F. App'x 368, 372 (6th Cir. 2013) (citing *Hicks v. Concorde Career Coll.*, 449 F. App'x 484, 487 (6th Cir. 2011)). Nolen, however, *did* address the one argument that Bard actually directed at Count IX, regardless of whether Nolen singled out that claim, in particular, in his argument. Bard itself, moreover, did not advance any argument specific to negligence *per se*, such that a claim-specific response would have been required. Bard simply included Count IX as one of the claims subject to a particular argument, and Nolen addressed that argument. The court, accordingly, will decline to grant summary judgment with regard to Count IX for the same reason that it did not grant summary judgment with regard to Counts III and IV: the applicability of Comment k has yet to be determined.

D. Punitive Damages

Finally, Bard argues that it is entitled to summary judgment with regard to Nolen's request for punitive damages because Tenn. Code Ann. § 29-39-104(d)(1)[2] forbids the award of punitive damages for an injury caused by a drug or device that

[2] Both Bard and Nolen acknowledge the possibility that a court could conclude that Arizona law, rather than Tennessee law, governs the issue of punitive damages in this case, but the parties agree that the two states have similar rules for these purposes. Neither party, moreover, argues that the line of reasoning that the court adopts *infra* would prevail under Tennessee law but *not* Arizona law. To the contrary, Bard

> [w]as manufactured and labeled in relevant and material respects in accordance with the terms of an approval or license issued by the federal food and drug administration under the Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040, compiled in 21 U.S.C. §§ 301-392, as amended, or the Public Health Service Act, 53 Stat. 682, compiled in 42 U.S.C. §§ 201-300cc-15.

Tenn. Code Ann. § 29-39-104(d)(1)(A). Nolen argues that that provision does not apply to the Meridian Filter because § 510(k) clearance does not constitute an "approval or license" issued by the FDA. Nolen also argues that, in any event, the court should not apply Tenn. Code Ann. § 29-39-104(d)(1) because portions of the broader statute of which it is a part were held to violate Article I, section 6 of the Tennessee Constitution in *Lindenberg v. Jackson National Life Insurance Co.*, 912 F.3d 348 (6th Cir. 2018).

It is questionable whether *Lindenberg*, which addressed only the constitutionality of Tennessee's statutory cap on punitive damages, should have any application to this case. The Sixth Circuit held, in that case, that the statute's cap on punitive damages "constitute[d] an unconstitutional invasion of the right to trial by jury," because it deprived a civil jury of the power to determine the appropriate amount of punitive damages. *Lindenberg*, 912 F.3d at 366. In other words, where the damages cap applied, courts were ordered, by the statute, to send a particular question to the jury but, at the same time, restrict the jury's power to answer that very question, which the Sixth Circuit held to improperly encroach on the jury's duties. *Id.* It is an altogether different thing, however, simply to provide that punitive damages are not available in certain situations as a matter of law, and it does not necessarily follow that one rule's unconstitutionality necessarily dictates the other's. The court, therefore, must determine whether Nolen's argument under the Tennessee Constitution should prevail on its own merits.

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suggests that the court's conclusion would be, if anything, even more clearly mandated under Arizona law. (*See* Doc. No. 91 at 10–11.)

"When resolving an issue of state law," a federal court must "look to the final decisions of that state's highest court, and if there is no decision directly on point, then [it] must make an *Erie* guess[3] to determine how that court, if presented with the issue, would resolve it." *In re Fair Fin. Co.*, 834 F.3d 651, 671 (6th Cir. 2016) (quoting *Conlin v. Mortg. Elec. Registration Sys., Inc.*, 714 F.3d 355, 358–59 (6th Cir. 2013)). Nolen has not cited any Tennessee Supreme Court caselaw suggesting that the Tennessee Constitution forbids the establishment of a statutory defense to the assessment of punitive damages, as long as the jury itself is permitted to determine any factual issues underlying that defense. Nor has Nolen identified any general trend or principle in the precedents of the Tennessee Supreme Court suggesting that that court would be persuaded by such an argument. Quite to the contrary—since *Lindenberg* was decided, the Tennessee Supreme Court has been overtly critical of the Sixth Circuit's reasoning, calling it "unpersuasive" and declining to adopt the Sixth Circuit's interpretation of the Tennessee Constitution in the Tennessee Supreme Court's consideration of a challenge to a similar statutory damages cap. *McClay v. Airport Mgmt. Servs., LLC*, 596 S.W.3d 686, 693 n.6 (Tenn. 2020). This court, therefore, finds it very unlikely that the Tennessee Supreme Court would embrace the holding in *Lindenberg* or extend it to invalidate even more statutory provisions. Regardless of what this court would decide if federal law were at issue, Nolen's argument based on the Tennessee Constitution is unavailing pursuant to the court's obligation to try to reach the conclusion that the Tennessee Supreme Court would reach.

The determinative question in this case, therefore, is whether § 510(k) clearance falls within the definition of an FDA "approval or license," as used in Tenn. Code Ann. § 29-39-104(d)(1). Neither "approval" nor "license" has a statutory definition for the purposes of

[3] "*Erie* guess" refers to *Erie R.R. Co. v. Tompkins*, 304 U.S. 64 (1938).

Tennessee's statutes limiting noneconomic damages. *See* Tenn. Code Ann. § 29-39-101. If one limits those terms to their use in ordinary speech, however, it seems clear that authorization to market a product pursuant to the § 510(k) process is, in fact, a form of "approval." Indeed, as Bard points out, the U.S. Supreme Court itself has referred to "§ 510(k) approval" in its opinions. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 322 (2008); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001).

Nolen's argument, therefore, hinges on the premise that, when the Tennessee General Assembly used the term "approval" in Tenn. Code Ann. § 29-39-104(d)(1), it was using a term of art specific to the pharmaceutical and medical device fields, pursuant to which "approval" would refer only to a product's satisfying the "rigorous" standards of "the 'premarket approval,' or 'PMA' process." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996); *see* 21 C.F.R. § 807.97 ("Any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding."); *N. Am. Med. Corp. v. Axiom Worldwide, Inc.*, 522 F.3d 1211, 1225 (11th Cir. 2008) ("The DRX 9000 is a Class II medical device, which is only eligible for FDA 'clearance' rather than FDA 'approval;' FDA approval is a separate process that applies only to Class III devices."); *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 762 (S.D.W. Va. 2014) (holding, in the context of a Texas tort statute, that "[c]learance through [§] 510(k) notification . . . does not constitute FDA 'approval' of the device"). The distinction between PMA and § 510(k) clearance is significant and could substantially affect the scope of Tennessee's punitive damages bar; "[i]n 2005, for example, the FDA authorized the marketing of 3,148 devices under § 510(k) and granted premarket approval to just 32 devices." *Riegel*, 552 U.S. at 317 (citing P. Hutt, R. Merrill, & L. Grossman, Food and Drug Law 992 (3d ed. 2007)).

"[A]lthough the [§ 510(k)] process is . . . not a rubber stamp program . . . , it does operate to exempt devices from rigorous safety review procedures." *In re C.R. Bard, Inc., MDL. No. 2187, Pelvic Repair Sys. Prod. Liab. Litig.*, 810 F.3d 913, 920 (4th Cir. 2016). As one circuit court of appeals explained:

> [T]he PMA and 510(k) processes have distinct requirements and different goals. PMA "*is* federal safety review," *Riegel*, 552 U.S. at 323, whereas "the 510(k) process is focused on *equivalence*, not safety," *Lohr*, 518 U.S. at 493 (quotation omitted and alteration adopted). Indeed, "devices that enter the market through § 510(k) have never been formally reviewed . . . for safety or efficacy." *Riegel*, 552 U.S. at 323 (quotation omitted). Rather, the 510(k) exemption is "intended merely to give manufacturers the freedom to compete, to a limited degree, with and on the same terms as manufacturers of medical devices that [previously] existed . . . ." *Lohr*, 518 U.S. at 494.

Eghnayem v. Bos. Sci. Corp., 873 F.3d 1304, 1317 (11th Cir. 2017) (formatting of citations altered). The court, therefore, must determine whether the Tennessee General Assembly's reference to "approval or license" by the FDA includes clearance through § 510(k), a process by which the FDA does, in fact, authorize devices for sale and use but which is distinct from the rigorous safety review that forms the bedrock of the FDA's approval of new medical devices.

As with this court's reading of the Tennessee Constitution, the court is required to try to interpret Tenn. Code Ann. § 29-39-104(d)(1) in the manner that the Tennessee Supreme Court would. Although the question is certainly debatable, the court's best guess is that the Tennessee Supreme Court would be more likely to adopt the more expansive interpretation of "approval or license" that would include § 510(k) clearance. First, it is persuasive that Tenn. Code Ann. § 29-39-104(d)(1) uses only the generic word "approval," rather than the more specific and specialized term "premarket approval." The use of the more general term suggests that the General Assembly was using language in its ordinary sense, not in the more specialized parlance found in federal medical device statutes and regulations. Moreover, there is a plausible argument that the key word

in "premarket approval" is not "approval," but "premarket." In that light, § 510(k) clearance is, in fact, a form of "approval"—just not approval that is "premarket," because the § 510(k) process assumes that a substantially equivalent device is *already* on the market. The court is also persuaded by the fact that the broader statutory scheme in which Tenn. Code Ann. § 29-39-104(d)(1) appears is not primarily a scheme for regulating drugs and medical devices, but for defining the substance and procedures of tort law more generally. The fact that the relevant statutes are ones of broad, general applicability makes it less likely that the General Assembly would have intended to use "approval" in a specialized sense.

The only way that the General Assembly could have intended to use "approval" narrowly here would have been if that legislative body had specifically had the distinction between PMA and lesser forms of FDA review in mind. But if the General Assembly was that far "into the weeds" of federal pharmaceutical law, why did it not more clearly indicate that it was drawing such a distinction? Why did it not just say "premarket approval" or cite the relevant subsections, as opposed to merely saying "approval" and citing generally to the Food, Drug, and Cosmetics Act as a whole? Nolen's argument requires the court to assume that the General Assembly was cognizant of, and intended to invoke, a counterintuitive, formal distinction used only in federal medical device law, while, at the same time, being unusually casual and imprecise about the way it referred to that distinction. That reading strikes this court as implausible, and the court's best prediction, based on the currently available clues, is that the Tennessee Supreme Court would agree and hold that "approval" is used in an ordinary sense to encompass § 510(k) clearance.

The court accordingly construes Tenn. Code Ann. § 29-39-104(d)(1) to set forth a defense to punitive damages that can be satisfied by establishing that the device at issue was "approved" by the FDA through the § 510(k) process. That determination, however, does not alone entitle

Bard to summary judgment. The same subsection that provides a defense to punitive damages based on FDA approval includes an exception stating that the defense

> shall not apply in an action against a manufacturer of a drug or device, if, at any time before the event alleged to have caused the harm, the manufacturer, in violation of applicable regulations of the food and drug administration:
>
> (A) Withheld from the food and drug administration information known to be material and relevant to the harm that the claimant allegedly suffered; or
>
> (B) Misrepresented to the food and drug administration information of that type.

Tenn. Code Ann. § 29-39-104(d)(2). Nolen has produced evidence that Bard was aware of and did not disclose to the FDA the full risks related to the G2 lines of filters' inadequate anchoring mechanism. (Doc. No. 92 ¶¶ 11, 20–26.) He has, therefore, at least arguably raised a contested issue with regard to whether the statutory exception to the defense, as written, should apply.

As Bard points out, however, that exception raises yet another difficult question about the interplay between state and federal law. The U.S. Supreme Court and the Sixth Circuit have both held that a state's laws will be preempted if they veer too far into the realm of policing a party's actions during the FDA review process, which those courts recognize as particularly within the domain of the FDA itself and, more generally, the federal government and federal law. *See Buckman*, 531 U.S. at 350 ("State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives."); *Garcia v. Wyeth-Ayerst Lab'ys*, 385 F.3d 961, 967 (6th Cir. 2004) (holding that exception to Michigan liability shield for FDA-approved products was preempted because it was based on the defendant's alleged wrongdoing before the FDA). There is little doubt that Tennessee's statute, as written, at least risks running afoul of that rule; indeed, Tennessee's statute appears to fall squarely within the Sixth Circuit's holding in *Garcia v. Wyeth-Ayerst*, which, like this case, involved an exception to a statutory safe harbor based on FDA approval. The Sixth Circuit held that a state statute that

creates a defense based on FDA approval cannot include an exception to that defense that calls on the court to independently evaluate the propriety of a party's actions before the FDA, because doing so would invade an area that federal law has reserved to itself. *Garcia*, 385 F.3d at 967. Applying Tenn. Code Ann. § 29-39-104(d)(2) wholly as written would violate the same principle.

In *Garcia*, however, the Sixth Circuit stressed that not every application of such a statute would be preempted and that a court can, rather than disregarding the relevant provision entirely, limit its application to those situations in which preemption would not occur. Specifically, the Sixth Circuit held only that federal law preempts a state-law distinction that depended on a *court's* finding of wrongdoing before the FDA, which "would raise . . . inter-branch-meddling concerns." *Garcia*, 385 F.3d at 966. In contrast, however, the Sixth Circuit held that a state statute could include a distinction based on wrongdoing before the FDA as long as it relied solely on the FDA's *own* finding of wrongdoing to determine whether that provision should apply. *Id.* Accordingly, for example, a provision like Tenn. Code Ann. § 29-39-104(d)(2) could permit punitive damages in a case arising out of an FDA-approved device based on the fact that "the *FDA itself*" made a determination that the manufacturer withheld information, but the same provision could not allow punitive damages based solely on the court's independent finding that such witholding had occurred. *Id.*

Nolen has identified evidence that, "[i]n 2015, [the] FDA found that Bard's adverse event reporting practices . . . resulted in the failure to properly report to [the] FDA serious injuries resulting from the use of its retrievable filter line," and Nolen asserts that those same faulty practices extended back to before his injury. (Doc. No. 92 ¶ 56.) Specifically, Nolen has produced an FDA form and letter memorializing various shortcomings of Bard's reporting. (Doc. No. 83-20; Doc. No. 85-25.) None of the events discussed therein, however, actually occurred "before the

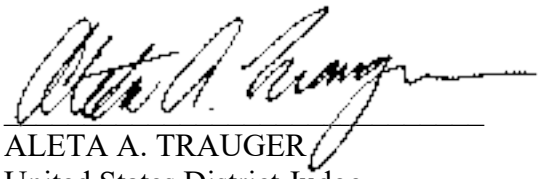
event alleged to have caused the harm" in this case, as required by Tenn. Code Ann. § 29-39-104(d)(2). Nolen, rather, asks the court to permit a factfinder to extrapolate the FDA's 2015 findings backwards to conclude that Bard withheld relevant information prior to Nolen's injury. Such an inference, however reasonable as it might be from a purely factual perspective, would run afoul of the rule set forth in *Garcia* that, in order to avoid preemption, a state law that draws the line between liability and non-liability based on wrongdoing before the FDA must rely only on the FDA's own finding of wrongdoing to do so.[4] Nolen, therefore, has not identified a disputed issue of material fact with regard to the applicability of Tenn. Code Ann. § 29-39-104(d)(1) and (2), as modified by federal preemption. The court will grant Bard summary judgment with regard to punitive damages.

IV. CONCLUSION

For the foregoing reasons, the defendants' Motion for Summary Judgment (Doc. No. 66) will be granted in part and denied in part, and the defendants will be granted summary judgment with regard to Counts I, V, VI, VIII, X, XI, XII, XIII, and XIV, as well as Nolen's claim for punitive damages. The defendants are denied summary judgment with regard to the remaining claims.

[4] Similarly unavailing is Nolen's brief attempt to identify a disputed issue of material fact with regard to whether the Meridian Filter that Nolen received was "manufactured and labeled in relevant and material respects in accordance with the terms of [its] approval." Tenn. Code Ann. § 29-39-104(d)(1). Nolen suggests that Bard cannot satisfy that requirement because there *were no* aspects of the filter's § 501(k) clearance that were "relevant and material" to the risks at issue in this case—and, therefore, the device could not have been sold "in accordance with" relevant and material requirements. This case, however, is about the core functionality of the filter—its ability to stay where and how it was placed. Although § 510(k) clearance is focused on equivalence rather than safety or efficacy in and of themselves, it does so because equivalence is defined in relation to a preexisting device that has itself proven to be safe and effective. The terms of the clearance, therefore, bore directly on the issues underlying Nolen's injury, and selling the device in accordance with that clearance was selling it in accordance with the terms of the relevant approval.

An appropriate Order will enter.



ALETA A. TRAUGER
United States District Judge